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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) WARNER ET AL. 09/859,701 Office Action Summary Examiner Art Unit Christine Foster 1641 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 02 March 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. 6) Claim(s) 1-20 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/fi.iall Date ______.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

5) Notice of Informal Patent Application

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

 A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/2/2009 has been entered.

Priority

2. The present application was filed on 5/16/2001. No priority claims have been made.

Terminal Disclaimer

The terminal disclaimer filed on 3/2/2009 disclaiming the terminal portion of any patent
granted on this application which would extend beyond the expiration dates of Application Nos.
11/974,156 and 10/880,388 has been reviewed and is accepted. The terminal disclaimer has
been recorded.

Objections/ Rejections Withdrawn

 The rejections under § 112, 2nd paragraph have been obviated by Applicant's amendments.

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The provisional obviousness-type double patenting rejections over copending Application
 Nos. 11/974,156 and 10/880,388 have been withdrawn in response to Applicant's filing of the above-mentioned terminal disclaimer.

Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 7. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.
- 8. Claims 1 and 11, as instantly amended, recite exposing a plurality of "binder-free" receptors to at least one binder in step (a). Applicant's reply does not indicate where support may be found for the limitation that the receptors are "binder-free", and the Examiner was unable to find support in the specification or claims as originally filed for the following reasons.

The specification does not employ the terminology "binder-free". When the claim terminology "binder-free" is given its broadest reasonable interpretation, receptors that are "binder-free" would encompass not only those receptors that have not yet been bound to the binder, but also receptors that are not bound to or in contact with any other type of biomolecule or material. However, in all of the examples disclosed in the instant specification, the receptors

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provided were bound to beads (see, e.g., page 8, line 15). Because all of the disclosed examples involved receptors that would reasonably be considered to be bound to a binder (beads) in this manner, rather than being "binder-free", the specification fails to convey evidence of possession of methods in which a plurality of binder-free receptors are exposed to binder. Consequently, implicit or inherent support is not apparent because the claim terminology can be interpreted in a manner that would rule out all of the disclosed embodiments.

For all of these reasons, the specification fails to convey evidence of possession of the claimed subject matter.

Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claims 1-8, 10-18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by
 Goldin et al. ("Quantitation of Antibody Binding to Cell Surface Antigens by X-ray
 Fluorescence Spectrometry" *Biochimica et Biophysica Acta*, 552 (1979) 120-128; of record).

Goldin et al. teach a method of detecting binding, comprising the steps of exposing a plurality of receptors (2,4-dinitrophenol hapten receptors attached to the surface of CHO cells) to at least one binder (ferritin-labeled antibody) in order to form a binder-receptor complex. See the

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entire document, in particular the abstract; pages 121-122; and especially at the paragraph bridging pages 122-123. It is noted that one could consider either the 2,4-dinitrophenol moiety alone to be the receptors or alternatively, the CHO cells together with the attached moiety as receptors.

The specification does not disclose the terminology "binder-free" or provide a specific or limiting definition thereof. When this terminology is given its broadest reasonable interpretation, this can be interpreted as referring to the fact that the receptors are not initially bound to the binder, which describes the situation in Goldin et al. prior to exposure of the hapten-bearing CHO cells to ferritin-labeled antibody.

The ferritin-labeled antibody binder of Goldin et al. may be said to be "chemically associated" with a nonradioactive element in that ferritin contains iron, which is detectable by X-ray fluorescence (see page 121, last paragraph; pages 123-125; Figure 3, and especially at page 123, the first full paragraph).

Goldin et al. further teach washing the cell-antibody complexes and arraying the complexes onto a substrate (electron microscope grids). See page 122, last paragraph.

Binding of the antibody to the cells is then detected by measuring the X-ray fluorescence due to the heavy element (iron) in the labeled-antibody/ CHO cell complexes (see page 121, last paragraph; pages 123-125; Figure 3, and especially at page 123, the first full paragraph).

With respect to claims 2 and 12, 2,4-dinitrophenol as taught by Goldin et al. is an organic (carbon-containing) compound.

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With respect to claims 3-4 and 13-14, considering the CHO cells with attached hapten to represent the receptors, it is noted that such cells comprise DNA (for example), which is a polymer/oligomer of nucleic acids (see Goldin et al. at page 122, penultimate paragraph).

With respect to claim 5 and 15, 2,4-dinitrophenol may be considered a cell membrane receptor as it was attached to the plasma membrane of the CHO cells (page 122, penultimate paragraph). It is also asserted by the Examiner that this compound was known in the art to produce effects on living cells, such that it may also be considered a "drug".

With respect to claims 6-8, 10, 16-18, and 20, Goldin et al. teaches ferritin-labeled antibodies, which are polymers/oligomers of amino acids that in turn comprise carbon.

11. Claims 1-5, 9-15, and 19-20 rejected under 35 U.S.C. 102(e) as being anticipated by Sano et al. (US 6,391,590 B1) as evidenced by Sigma-Aldrich (Product information sheet, Material Safety Data Sheet, and Safety Statements for cadmium chloride (catalog No. 28811), retrieved from http://www.sigmaaldrich.com/ on 4/23/09).

Sano et al. teach methods of determining metal-binding activity of streptavidin-metallothionein chimeric protein, in which the receptors (i.e., chimeric proteins) are exposed to at least one potential binder, namely the metal ion Cd^{2+} which is provided as $CdCl_2$ during the course of protein purification (Example 2, see especially column 15, lines 11-16 and 30-42; and also at column 2, lines 40-54). The metal ion binder is made of the element cadmium (which is detectable by X-ray fluorescence) and would therefore be considered to be "chemically associated" with this element when this terminology is given its broadest reasonable interpretation.

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Sigma-Aldrich et al. is cited as an evidentiary reference to show that the metal ion binder Cd²⁺ as taught by Sano et al. is associated with an element that is nonradioactive. In particular, Sigma-Aldrich et al. provides evidence regarding the known properties of CdCl₂. See the first page, Product Information for Cadmium chloride, catalog No. 28811. This product information includes safety information. In the section entitled "Safety Statements," Sigma-Aldrich et al. list numerous possible safety warnings that the company uses to warn users about potential hazards of particular materials. To warn uses about materials that are radioactive, a particular pictogram is employed (see the section entitled "Pictograms and Hazard Codes"). This pictogram signaling radioactive materials is not included in the product information for cadmium chloride, indicating that this material is not radioactive. Furthermore, in the lengthy Material Safety Data Sheet for cadmium chloride which lists known hazards of this material, radioactivity is not mentioned. Therefore, in light of the evidence of Sigma-Aldrich et al., the binder taught by Sano et al. has a chemically associated element which is non-radioactive.

Sano et al. further teaches spotting (i.e. arraying) the proteins onto a substrate (polypropylene membrane). See Example 3, in particular at column 15, lines 58-61). The arrayed proteins were then subjected to quantitative X-ray fluorescence in order to determine the amount of metals in the sample spot (Example 3). This reads on the instantly claimed step of detecting an X-ray fluorescence signal generated by the detectable element, since the signal of the deposited protein-bound heavy metal ion (cadmium) is measured thereby. See also column 2, lines 55-67. Regarding the limitation that the receptor is initially "binder-free", the chimeric protein of Sano et al. would be considered to be initially unbound before it is contacted with the metal ion during dialysis. When the sample is then spotted onto a membrane after the dialysis step, protein bound

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to Cd^{2+} would be arrayed. See column 15. By this process, unbound metal ion would be separated form bound and unbound receptor.

With respect to claims 2-5 and 12-15, the chimeric protein taught by Sano et al. reads on the instant claims as proteins are carbon-containing polymers of amino acids.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all
 obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- Claims 1-8, 10-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,663,277).

Wang teach methods for detecting viruses and/or proteins, in which a plurality of viruses or proteins (i.e., receptors) in a specimen is exposed to an extended solid phase component (i.e., substrate) which is coated in at least one location with antiviral or antiprotein antibody (see

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especially the abstract; column 2, lines 16-67; column 3, lines 25-57; and claims 1, 20, and 39-40 in particular). This step in which viruses in the sample are bound to the solid phase via the antiviral or antiprotein antibodies reads on the claimed step of "arraying" the receptors on a substrate when given its broadest reasonable interpretation. For example, Wang teaches a solid phase that is a dipstick having two locations at which the antibody is coated (see Figure 3 and column 3, lines 65-68), such that the viruses would be bound to the dipstick in an array or pattern corresponding to the locations at which the antibody is coated. Different viruses can also be detected simultaneously by using different antiviral antibodies (column 7, lines 39-51), which would also be considered to represent an array absent a specific or limiting definition for this term.

The virus or protein receptors attached to the extended solid phase would be considered to be "binder-free" in that they are not yet bound to the binder, for example (see below). In particular, because the instantly disclosed embodiments involve the use of receptors which are bound to beads, the terminology "binder-free" can be reasonably interpreted in this manner and is not seen to limit the claims to those receptors which are not bound or attached to any other material.

Wang further teaches exposing the arrayed receptors to at least one potential binder, namely the same antibody coated onto a mobile solid phase of dispersed microspheres (see in particular column 2, lines 53-59; column 4, line 61 to column 5, line 2). Further, Wang repeatedly contrasts their disclosed methods with radioimmunoassay, such that it can be at once envisaged that the antibody-microspheres are nonradioactive.

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In one embodiment, the microspheres in the binder may be doped with metal elements so as to enable detection by X-ray fluorescence using appropriate detection equipment (i.e., having a chemically associated element detectable by X-ray fluorescence; see column 6, lines 12-20; column 7, lines 21-59; and claims 1 and 20, for example). The antibody-coated microspheres doped with metal elements therefore read on the instantly claimed "binder having a chemically associated and nonradioactive element detectable by X-ray fluorescence". Detection of the X-ray fluorescence of the metal element labels in the microspheres indicates that binding between the receptors and the solid phased antibody(ies) has occurred (i.e., detecting an X-ray fluorescence signal generated by the detectable element in the bound microspheres). See also claim 20.

Wang further teaches of separating the solid phase substrate from the specimen and from unbound microspheres by washing (column 2, lines 60-63; and claims 4 and 20 in particular). Since the solid phase substrate contains bound receptor, unbound binder would be removed.

The teachings of Wang differ from the claimed invention in that the prior art methods involve first arraying the receptors on the extended solid phase, followed by contacting with the plurality of antibody-microsphere binders. By contrast, the instant claims require that the bound receptor (after exposure to binder) be arrayed onto the substrate.

However, the courts have ruled that changes in the sequence of adding ingredients or in the order of performing process steps is considered only routine expedient, and Applicant has not demonstrated criticality with regard to the order in which the receptors are contacted with binder and with the substrate. See MPEP 2144.04.

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention by first contacting the receptors of Wang with binder (antibody-coated

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microspheres), followed by arraying of bound receptor onto the solid phase support. Absent evidence of criticality, the selection of any order of performing process steps is *prima facie* obvious. Consequently, one of ordinary skill in the art would have found it obvious to select any order of contacting receptor, binder, and substrate out of the course of routine optimization.

With respect to claims 2-5 and 12-15, Wang teaches detection of proteins (e.g. viral glycoproteins), which read on the instant claims as proteins are carbon-containing polymers of amino acids (see Wang at claims 20 and 40 and column 8, lines 4-36). Similarly, the antibodies taught by Wang read on claims 6-8, 10, 16-18, and 20 since antibodies are also proteins.

Response to Arguments

Applicant's arguments filed 3/2/2009 have been fully considered. With respect to the rejections of claims 1-5, 9-15, and 19-20 under 35 U.S.C. 102(e) as being anticipated by Sano et al. (US 6,391,590 B1), Applicant's arguments (Reply, pages 7-9) have been fully considered but are not persuasive.

Applicant argues that Sano is not anticipatory because the methods disclosed therein are directed toward the conjugation with or radioactive-labeling or tagging of biological material containing biotin with various heavy metal ions, their stable isotopes, or their radioisotopes. Applicant argues that the metal ion Cd²⁺ taught by Sano is in fact a radioactive label or tag, and that Sano detects X-ray fluorescence from such a radioactive tag rather than directly from a binder (Reply, page 8).

This is not found persuasive while Applicant apparently perceives the metal ion Cd²⁺ taught by Sano to represent a "tag" or "label", the instant claims fail to rule out such a material. In particular, the claims recite a "binder having a chemically associated and nonradioactive

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element". As taught in Sano, Cd^{2+} binds to proteins and is thus a "binder". Further, this metal ion is made up of the nonradioactive element cadmium; as such, Cd^{2+} may be said to be "chemically associated" with cadmium when this terminology is given its broadest reasonable interpretation. In addition, it is apparent that metal ions (as in Sano) are suitable binders according to the instant invention, as recited in instant claims 9-10 and 19-20.

In regards the argument that the metal ion Cd^{2+} taught by Sano is radioactive, as evidenced by Sigma-Aldrich et al. (discussed above), the binder taught by Sano et al. is not radioactive. The arguments of counsel do not constitute sufficient evidence to the contrary.

For all of these reasons, there is insufficient evidence of record to support Applicant's position that the material taught by Sano is a radioactive tag or label and not a binder as claimed.

Applicant further argues that attachment of a fluorescent tag to a chemical or receptor could result in conformational changes that affect the ability of the chemical or receptor to bind other materials (Reply, page 9, first paragraph). Such arguments are not found persuasive because it is unclear how they address the rejection at issue. In Sano et al., the binder Cd²⁺ is not conjugated to another material and is therefore not "tagged"; nor is it attached to another material such that it would be considered to itself represent a tag. Therefore, the arguments are not on point because they do not address the particular teachings of the reference.

With respect to the rejections of claims 1-8, 10-18, and 20 are rejected under 35 U.S.C.
 103(a) as being unpatentable over Wang (US 4,663,277), Applicant's arguments (Reply, pages 9-16) have been fully considered but are not persuasive.

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Applicant argues for the existence of long-felt but unsolved needs met by the present invention (Reply, pages 10-11). The Examiner finds insufficient evidence of long-felt need, for the following reasons.

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution (MPEP 716.04). Here, no evidence has been advanced to document the existence of long-felt need. Applicant does not explain with any particularity what specific art recognized problem is at issue. Furthermore, there is no showing, for example, that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04.

In addition, the long-felt need must not have been satisfied by another before the invention by Applicant. In the instant case, the claimed invention has been found to be anticipated by Sano et al. and Goldin et al. for the reasons discussed above. Therefore, there is insufficient evidence to conclude any long-felt need was not previously satisfied by another.

For all of these reasons, the arguments of counsel do not constitute sufficient evidence of long-felt need to outweigh the evidence of obviousness.

Applicant further argues that Wang fails to teach or suggest every element of the invention as claimed (Reply, pages 13 and 15), which is not found persuasive because this is not the standard for obviousness. Rather, "The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively

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would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

Similarly, Applicant's arguments that Wang fails to teach or suggest the modification proposed by the Examiner, i.e. the particular order of steps as claimed (Reply, pages 13 and 15) are not persuasive because "There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention.

Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdiqital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997). In the instant case, the courts have ruled that changes in the order of performing process steps is considered only routine expedient, and Applicant has not demonstrated criticality with regard to the order in which the receptors are contacted with binder and with the substrate. See MPEP 2144.04.

In this regard, Applicant further argues that as a matter of logic, immobilizing the receptor onto a substrate first and then exposing the receptor to potential binders would prevent the receptor and the binder from actually binding, since the receptor would necessarily be immobilized (Reply, page 13, second paragraph).

The Examiner finds insufficient evidence to support this contention that immobilized receptors would be incapable of binding. To the contrary, Wang et al. successfully detected complexes formed subsequent to receptor immobilization. Similarly, the specification incorporates by reference U.S. Patent 5,143,854 and describes this work as a screening method in which a polypeptide array (i.e., arrayed on a substrate) is exposed to a ligand in order to determine which members of the array bind to the ligand (see page 2). Furthermore, it was well

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known in the art to immobilize receptors onto substrates for use as capture agents in binding assays; e.g., in ELISA assays in which capture antibodies are first immobilized to a substrate and then used to bind to antigens in an added sample. Indeed, in the disclosed examples of the specification the receptors are provided immobilized onto beads, yet remain capable of binding.

Applicant further traverses the Examiner's interpretation of the term "untagged" (Reply, pages 13-15). Applicant's arguments are acknowledged but are currently moot as the claims do not currently recite this claim terminology.

Applicant further argues that the Examiner's combination would require a substantial reconstruction and redesign of the elements of Wang and would also change its principles of operation; and that this would not be an "expected" result (Reply, paragraph bridging pages 15-16). Such arguments of a general are not persuasive as they do not particularly point out in what way a change in the order of operation of process steps would represent a 'substantial redesign' of the method of Sano. Further, it is not specifically explained in what way the claimed invention represents an unexpected or unpredictable result. Therefore, the general arguments by counsel are not seen as persuasive evidence of non-obviousness or of unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached at (571)

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272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine Foster/ Examiner, Art Unit 1641

/Christopher L. Chin/ Primary Examiner, Art Unit 1641